

REMARKS

Claims 18-31 and 33-34 are pending in the application.

Claim Amendments

Claim 18 has been amended to remove recitation of “an internal cone” and to recite “inserted into the connection-side opening” and “but does not penetrate the slit of the self-sealing membrane.” Support for the amendment is found at least at paragraph [0029] and Figs. 6a-6b.

Claim Rejections Under 35 USC 103

Claims 18-34 were rejected under 35 USC 103(a) as being unpatentable over DE10030474 to Rahimy in view of US5100394 to Dudar, et al. Claim 32 is canceled. The rejection is respectfully traversed.

A problem addressed by the invention is to provide a connector for medical liquid-containing packages, in particular, infusion and transfusion bags, which is able to be produced cost-effectively and handled in a straightforward and safe manner and permits a rapid supply of, in particular, viscous active substances, and with which the risk of injury to the nursing staff and damage to the package is low.

In an embodiment of Applicants' approach, a connection piece 13 of a connection part 1 and self-sealing membrane 8 are arranged and designed in such a way that the conical shaft 31 of a syringe 32 inserted into a connection-side opening 1a of the connection part opens the slit membrane 8, but does not penetrate the slit of the self-sealing membrane (see Figs. 6a and 6b). That is, the conical shaft does not pass through the slit of the membrane. Since the slit membrane 8 is not penetrated by the shaft of the syringe, the membrane closes in a sealing fashion when pulling out the shaft of the syringe. After withdrawal of the shaft, the membrane completely closes and thus prevents liquid from leaking out of the package.

Rahimy discloses a connector with a connection part 2 with a channel-shaped recess 8 in which a self-sealing membrane 4 is arranged. The connector further comprises a break-off part 6 that is connected to the connection part 2 and closes the recess 8.

The Examiner acknowledged that Rahimy fails to disclose that the membrane comprises a slit to receive a syringe and looks to Dudar which discloses a connector with a channel and a membrane with a resealable opening or slit 66 that allows repeated access with a blunt cannula.

The Examiner stated that Dudar discloses that when a blunt cannula enters the membrane, it separates the slit, allowing the membrane to separate without the cannula penetrating the surface of the septum (*emphasis added*). Applicants disagree.

The cannula in Dudar clearly penetrates (passes through) the slit of the septum, as shown in Figs. 4B, 5B and 13. This is understood from disclosures in Dudar:

The sealing member also is formed with a curved exterior peripheral surface such that the blunt cannula can be sealingly inserted through the opening and placed in fluid flow communication with the flow path. (Col. 2, lines 43-47)

The cylindrical blunt piercing member 98 can slidably engage the pre-slit septum 52, best illustrated in FIG. 4B, thereby extending through the preformed opening 66 therein. As illustrated in FIG. 4B, when the piercing member 98 slidably engages and pierces the septum 52, the region 52a deforms by expanding into and filling, at least in part, the annular channel 62. The deformation facilitates insertion of the piercing member 98 through the slit 66. Subsequent to the piercing member 98 slidably engaging the injection site 34, the interior region 90 of the syringe 82 is in fluid flow communication with the flow path 68 of the injection site 34 via flow paths 88a and 99 respectively of the syringe and the blunt piercing member 98. (Col. 8, lines 13-26)

FIGS. 5A and 5B illustrate the pre-slit injection site 34 used in combination with a blunt cannula 80a. The cannula 80a includes piercing member 98a and manually operable elongated locking members 100a and 100b. Curved end regions 100c of the members 100a and 100b slidably engage the second end 44 of the housing 40 when the piercing member 98 of the blunt cannula 80a has been forced through the pre-formed opening 66, best illustrated in FIG. 5B. (Col. 8, lines 52-62)

Rahimy and Dudar, et al. do not teach, or even suggest, designing and arranging the connection part such that the shaft of a syringe inserted into the connection part opens the membrane, but does not penetrate the slit of the membrane, as required by amended claim 18.

Moreover, it should be noted that the connector according to the invention operates in connection with a conical shaft of a syringe. In contrast, Dudar is not intended for inserting the conical shaft of syringe rather than the blunt cannular of a coupling system (Figs. 12 and 13) or an adapter spike (Fig. 36). Furthermore, in contrast to the invention, the connectors of Rahimy operate with a needle of a syringe (injection site of Fig. 1) or the spike of a transfer device (withdrawal device of Fig. 3). Both such connectors of Rahimy are not intended to be used in connection with the conical shaft of a syringe.

In summary, none of the cited documents teach, or even suggest, the arrangement of the membrane in the connection piece of the connection part according to the invention of amended claim 18. In addition, claims 19-31, 33-34 depend from and include all of the elements of base claim 18, and therefore are patentable over the combination of Rahimy and Dudar for at least the same reasons as stated above for claim 18. Reconsideration of the rejection under 35 USC 103 is respectfully requested.

Claims 18-34 were provisionally rejected on the ground of non-statutory double patenting relative to co-pending application 10/514,817. Applicants defer addressing the rejection until allowable subject matter is determined by the Examiner.

Information Disclosure Statement


An Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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